05-23-00

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JC711 U.S. PTO 05/22/00

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

Atty. Docket No. 1002-111

JC812 U.S. PTO 09/575429 05/22/00

Sir:

Transmitted herewith for filing is the patent application of
Slide-in Cassette for a Cup For Testing of Drugs of Abuse

Inventor(s): Jeffery A. Konecke

Enclosed are:

[x] The specification (consisting of 11 pages and 16 claims (contained on on pp. 8 to 10).

[x] 3 sheet(s) of drawing(s).

[x] A Declaration and Oath of the Inventors
[x] Signed [ ] Unsigned

[x] Assignment of the invention to
Forefront Diagnostics Inc.

[x] A power of attorney.
To: Ying-kit Lau, J.D., Ph.D.

[ ] A certified copy of the _____ application filed _____[Serial No. _____] under which applicant claims priority.

[ ] A verified translation of the _____application.

[ ] A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR. 1.27.

[ ] Other:_____
_____

The filing fee has been calculated as shown below:

	Col. 1	Col. 2	SMALL ENTITY			OTHER THAN A SMALL ENTITY		
FOR	NO. FILED	NO. EXTRA		RATE	FEE	OR	RATE	FEE
BASIC FEE				$345	$345		$760	$
TOTAL CLAIMS	16-20		x	$9	0	OR x	$18	
INDEP. CLAIMS	1-3		x	$39	0	OR x	$78	
MULT.DEPENDENT CLAIMS PRESENTED			+	$130	0	OR +	$260	
	ASSIGNMENMT		+	$40	40	+	$40	
			TOTAL $		**385**	**TOTAL $**		

CERTIFICATE OF MAILING UNDER 37 CFR §1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee" mailing Label No. EL305877019US addressed to the: Commissioner of Patents and Trademarks, Washington, DC 20231 on May 22, 2000.

By _____
Doris Lau

[ ] Please charge my ***Deposit Account No.*** _____ in the amount of $_____. A duplicate copy of this sheet is enclosed.

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[ ] Any additional filing fees required under 37 CFR 1.16.

[ ] Any patent application processing fees under 37 CFR 1.17.

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Attorney's Docket No. 1002-111-APP **PATENT**

☒ Applicant Jeffery A. Konecke ☐ Patentee _____

☐ Application No. ☐ Patent No. _____

☐ Filed on ☐ Issued on _____

Title: SLIDE-IN CASSETTE FOR A CUP FOR TESTING OF DRUG OF ABUSE

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c))—SMALL BUSINESS CONCERN

I hereby declare that I am

☐ the owner of the small business concern identified below:

☒ an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Small Business Concern Forefrong Diagnostic, Inc.

Address of Small Business Concern 23561 Ridge Route Drive, Suite D

Laguna Hills, CA 92653

I hereby declare that the above identified small business concern qualifies as a small business concern, as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office under Sections 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to, and remain with, the small business concern identified above, with regard to the invention described in

☒ the specification filed herewith, with title as listed above.

☐ the application identified above.

☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c), if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: *Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)*

Each such person, concern or organization having any rights in the invention is listed below:

☒ No such person, concern, or organization exists.

☐ Each such person, concern or organization is listed below.

Name _____

Address _____

_____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

Name _____

Address _____

_____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small business entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing Jeffery A. Konecke

Title of Person if Other Than Owner President

Address of Person Signing 904 S. 3rd St.

Mebane, NC 27302

SIGNATURE Jeffery A. Konecke Date 5/15/00

SLIDE-IN CASSETTE FOR A CUP FOR TESTING OF DRUGS OF ABUSE

1. FIELD OF THE INVENTION

This invention relates to the art of handling, testing, and transporting fluid specimens. More particularly, it relates to a cup with a slide-in cassette to provide testing of drugs of abuse in bodily fluids, such as urine, blood, saliva, etc.

2. BACKGROUND OF THE INVENTION

Fluid specimens, particularly urine, are normally collected in containers, vials or cups. When it is desired to run tests on liquid or fluid specimens contained in the cups, the lids are normally removed and specimen samples are taken out of the cups and transferred to a test apparatus. In the Instacheck® Drug Screen Drug Test, a urine sample from a cup is drawn up in a pipette and 3-4 drops (~0.2 ml) are then dispensed onto the sample well. The urine then travels up a chemical strip for 3-8 minutes. The chemical strip was pre-coated with drug conjugate on the test band. A colored anti-drug monoclonal antibody colloidal gold conjugate pad is placed at one end of the strip. In the absence of the drug in the urine, the colored antibody colloidal gold conjugate moves along the sample solution upward on the strip chromoatographically by the capillary action to the immobilized drug conjugate zone on the test band region and attaches to the drug conjugate to form a visible line on the antibody complexes with the drug conjugate. Therefore, the formation of a visible precipitate in the test zone occurs when the test urine is negative for the drug. When drug is present in the urine, the drug/metabolite antigen competes with drug conjugate on the test band region for the limited antibody sites on the antibody-colloidal gold conjugate. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A difficulty with the Instacheck® test is that the urine needs to be transferred from a cup onto test strips with the lid of the cup removed, thus exposing the operator and work area to possible contamination. Additionally, the specimen sample could become contaminated as well as the worker and the surrounding equipment. Furthermore, with lid removed, spillage and loss of the unique specimens may occur. Thus, it is the object of this invention to provide a custom designed integrated system composed of a custom collection cup used as a collection and testing vessel and a custom designed slide-in test cartridge to test for drugs of abuse and other chemical and biological substance in urine and other liquid mediums in a closed, safe and secure environment.

2. **Description of the Prior Art**

U. S. Patent No. 5,119,830 to Davis describes a specimen cup having a valve to selectively operated from outside the specimen cup to introduce fluid specimen for detection of drugs of abuse by chemical strips.

U. S. Patent No. 5,916,815 to Lappe describes a specimen cup to detect drugs of abuse using intentional false positive to initially preserve anonymity.

U. S. Patent No. Des. 404,812 describes a multiple drug test card to be housed in a cup for detection of drugs of abuse. It requires sliding a card through a slotted lid and thus exposure, spillage and contamination are possible. The card is neither sealed nor contained within the device and thus can contaminate specimen. Additionally, the card draws sample from the side and required both a maximum and minimum fill requirement which makes exposure and spillage a greater problem as user tries to fill container "just right". If the minimum and maximum fill marks are not followed the test will not function. Too little urine and the test does not run, too much and the test sample is contaminated. The card must be removed at the completion of the test cycle, resulting in exposure and contamination to user and work area. If the sample is positive, the cover is removed and a closed cover is placed on bottle. Again, exposure and spillage is a problem. Lastly again, the card is inserted in the middle of a low bottle resulting in difficulty

in reading result and often requiring the user to lift the card out to view or tip bottle to view. Either way exposure and spillage is a problem.

All of the above patents had to use very complicated and/or expensive collection/reagent system. They are troublesome to get quick and easy test results. Additionally, some result in difficulty in transporting or storing the fluid specimen.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a easy to use, inexpensive, integrated testing system comprised of a collection cup/testing vessel and a slide-in testing cassette housing the chemical/immunological test strips for the testing of drugs of abuse and other chemical and biological substances in urine and other liquid specimens/samples. The integrated system is composed of the custom test cup used to collect the sample and then the same cup is used as the testing vessel and ultimately as the storage and transport container. The test cup also can comprise a spill-prevention and over-fill prevention flap or float. This component is a movable device that is in a vertical position at the start of filling. As urine or other liquid sample is placed in the cup the "flap" will raise to a horizontal position. When raised it cuts off the available space in the cup and creates an artificially filled environment preventing additional liquid from being added to the cup. The cup is designed with a "flat" face, set back in the circular cup to move the viewing area closer to the test device while maintaining a circular type cup at the top and bottom for stability and ease of use. The "flat" viewing window also results in a ergonomically designed cup that is easier to handle when the subject is providing the urine or other sample. The inside bottom of the cup is designed with a sloped bottom (1-3 degrees) to allow for the urine sample or other liquid sample to be channeled towards the test cassette, thus allowing for testing when small volumes of specimen are given. The test cassette is uniquely designed to draw urine from the bottom, thus minimizing the amount of urine needed to perform the test. This design also eliminates the need for minimum sample volume requirements or having to tilt, turn or

invert the container to allow sample to contact the test strips. The card is hermetically sealed both around the entire perimeter as well as vertically between each test strips and horizontally below the test regions. This assures that each test strip is isolated within a unique test column and prevents any cross-contamination between the chemicals/substances contained within each test strip. The area of the card where the test regions of the test strips are viewed is covered with a clear material hermetically sealed to the face of the test card to prevent any direct contamination of the test strips from the sample or tampering with the test strips by the operator or donor. There is a sample "pooling" area at the bottom of the test cassette to allow urine or other liquid sample to migrate up to contact the test strips. This "pooling" area functions as an internal sample well. This allows the test strips to be completely enclosed in the device and eliminates any contact from the operator or donor which could cause contamination. Additionally, running horizontally above the "pooling" area is a "dam" designed to restrict the vertical flow of sample up the test strips and contain the sample in the "pooling" area.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features which are believed to be characteristic of the invention are set forth with particularity in the appended claims. The invention itself, however, both as to its organization and method of operation, may best be understood by reference to the following description, when taken in connection with the accompanying drawing in which:

FIG.1 is a prospective view of the cup for testing drugs of abuse and other chemical and biological substance of the present invention.

FIG.2 is a top prospective view of the specimen cup (with the top cover removed) of FIG.1; and

FIG.3 is a (bottom) prospective view of the slide-in cassette.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

A specimen cup (100) of the present invention includes a base container (112) and a lid (114). The specimen cup (100) is for collecting, testing, storing and transporting a urine specimen and other liquid within a container thereof. The base container (112) can optionally has an expanded sample collection portion to allow more urine to be collected. The lid (114) has threads (116) which mesh with threads (118) of the base container (112) to sealingly hold the lid (114) on the base container 112. In region A behind the chamber (104) to which the cassette (102) is hermetically sealed, there is a urine spill prevention flap or float (108) (see FIG. 2) to which the urine once entered into the sample collection portion will be prevented from splashing during transport or storage. The flap or float is free to travel vertically in region A under the pressure from the fluid specimen, such as urine.

The base container (112) and its lid (114) are constructed of a material which is transparent, and impervious to fluid specimens contained therein. The materials include but not limited to thermoplastics, specialty plastics, thermosets, engineering plastics.

Thermoplastics include but not limited to: polyamideimide (PAI), polyethersulfone (PES), polyarylsulfone (PAS), polyetherimide (PEI), polyarylate (PAR), polysulfone (PSO), polyamide (PA), polycarbonate (PC), styrene-maleic anhydride (SMA), chlorinated PVC (CPVC), poly(methylmethacrylate) (PMMA), styrene-acrylonitrile (SAN), polystyrene (PS), acrylonitrile-butadiene-styrene (PS), acrylonitrile-butadiene-styrene (ABS), poly(ethyleneterephthalate) (PET), poly(vinylchloride) (PVC), polyetherketone (PEK), polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE), poly(phenylene sulfide) (PPS), liquid crystal polymer (CCP), nylon-6,6, nylon-6, nylon-6,12, nylon-11, nylon 12, acetal resin, low and high density polypropylene (PP), high density polyethylene (HDPE), low density polyethylene (LDPE), polystyrene, ethylene-vinyl acetate, poly-vinyl-acetate, polyacrylic, etc., or a copolymer or a combination thereof.

Specialty plastics include but not limited to fluorocarbon polymers and infusible film products such as Kapton, Upilex polyimide film etc., a coplymer or a combination thereof. Thermosets include but not limited to phenolics, epoxies, urea-formaldehyde, silicones, etc., a copolymer or a combination thereof. Engineering plastics include but not limited to acetyl resins, polyamide, polyetherimides, polyesters, liquid crystal polymers, polycarbonate resins, poly(phenylene ether) alloys, polysulfone resins, polyamideimide resins, etc., a copolymer or a combination thereof .

The bottom floor (120) of the cup can be optionally sloped from the backside (122) downwardly at 1-3° towards the front side (124). This forces the fluid (by gravity) to moves forward, hence reduces the fluid specimen needed for the testing for drugs of abuse by the cassette. The front of the cup has a retracted flat face (200) designed to move the viewing area closer to the test cassette. The base and top of the cup remain circular to allow for use of standard covers and provide a stable base. Inside the cup are custom channels (156) used to guide and oriented the cassette in the device. The cassette is inserted into the cup (100) with its outside edges (150) anchored between the bars (158). The slot on the left side of the cassette will only align with the triple channel on the left side of the cup. The bars (158) ensure the cassette is inserted facing the correct way for viewing and ensure proper placement within the container. Because one of the fluids that may be tested is urine, as the urine cools in a closed environment condensation may occur. The tracks are designed to orient the cassette for viewing while allowing movement of air between the cassette and face of cup to prevent condensation forming on inside of cup. The chemical test strips (106) of various, flexible configurations such as 11-nor-Δ-9-tetra hydrocannabinol-9 carboxylic acid (THC), Cocaine (COC), Methamphetamine/amphetamine (MAP), 1-(1′- phenylcyclohexyl) piperidine (PCP), Morphine (MOR) etc. are housed in a custom cassette (126). The cassette has four distinct, isolated test channels (132, 134, 136 and 138) which house the test strips. Each test channel has a clear, sealed window for viewing the results. Each channel is hermetically sealed both vertically and horizontally

to ensure four unique test areas and prevent any direct or cross contamination. As seen in FIG. 3 the cassette is formed by an upper (128) and lower (130) member. Near the bottom of the cassette is a horizontally running "dam" (260) that when the upper and lower members are hermetically sealed together creates a sample "pooling" area (210). This "pooling" area (210) allows sample to contact the test strips while eliminating the need for the test strips (106) to be exposed. Thus the entire test strip is contained within the cassette eliminating potential contamination, adulteration or tampering. When the test card is inserted into the test container, the sample "pools" around the base of the test strips and wicks vertically up the strips. As the sample moves up the strip, the result is observed through the clear viewing windows. The clear viewing windows prevent direct contact with the test regions of the test strips either by the operator, donor or specimen.

During operation, a specimen, such as urine, is provided in the custom collection/test cup (100). The test cassette (126) is inserted into the test cup through custom bars (156) and the lid of the cup (114) is put in place. The urine specimen then enters the "pooling" areas (210) at the base of the test cassette and begins to wick up the test strips. When the urine contacts the test strips, the characteristics thereof, in conjunction with chemicals in the test strips causes the test strips to change color, thereby providing a visual indication to an operator in accordance with the precalibrated indicator marking beside the respective test strips corresponding to such characteristics. The changes in color are then easily observed and read by the operator through the transparent window on the test card and the face of the collection/test cup.

After testing is completed, the specimen can be stored, transported or disposed of in the collection/test cup used for this testing process. This eliminates having to remove the test device, change lids, transfer specimen or otherwise handle the urine sample in any way that could result in exposure or contamination to the operator, donor of surrounding environment.

It will be appreciated by those of ordinary skill in the art that the specimen cup of this invention allows collection, testing, transportation and storage of a fluid specimen, such as urine, with chemical strips of characteristics of the specimen without exposing it to the outside atmosphere, or having to come into direct contact with the specimen himself, thereby eliminating the possibility of contaminating him/her-self or surrounding equipment with the fluid specimen contained in the specimen cup, or possibly spilling and losing the entire unique specimen itself.

6. CLAIMS

Having described our invention, what we claim and desire by letter patent is:

1. A specimen cup for testing fluid specimen contained therein, said cup comprising a container used to collect a fluid specimen, a cassette hermetically sealed and custom fit to said container, said cassette further containing chemical strips means to provide an indication of a characteristic of said specimen regarding drug of abuses.

2. A specimen cup as in claim 1 wherein said bottom floor of said cup is sloping from the backside downwardly at 1-3° towards the front side allowing specimen to be channeled towards testing device.

3. A specimen cup as in claim 1 wherein said cup has a retracted flat face designed to move the viewing area closer to said cassette.

4. A specimen cup as in claim 1 wherein said cassette is inserted into said container through custom channels on said container to anchor said cassette's outside edges and orient cassette for proper testing and viewing.

5. A specimen cup as in claim 1 wherein said cassette comprising test strips used to test for THC, COC, MAP, PCP and MOR.

6. A specimen cup as in claim 1 wherein said cassette comprising a plurality of isolated test channels which house said test strip for testing drugs of abuse.

7. A specimen cup as in claim 6 wherein each isolated test channels has a clear, sealed window hermetically sealed to face of cassette for viewing the results of the test.

8. A specimen cup as in claim 7 wherein said clear, sealed window is formed by a transparent fluid-resistant sheet laying on top of said test strips to prevent fluid specimen from accidentally spill and contaminate the strips.

9. A specimen cup as in claim 1 wherein said cup further comprising a flap to which once fluid specimen entered into said cup, said flap will prevent said fluid specimen from splashing during collection, testing, transport and storage.

10. A specimen cup as in claim 1 wherein said cup further comprising a float to which once fluid specimen entered into said cup, said float will prevent said fluid specimen from splashing during collection, testing, transport and storage.

11. A specimen cup as in claim 1 wherein said cup is constructed of a material selected from the group comprising thermoplastics, specialty plastics, thermosets, and engineering plastics.

12. A specimen cup as in claim 10 wherein said thermoplastics is selected from the group comprising polyamideimide (PAI), polyethersulfone (PES), polyarylsulfone (PAS), polyetherimide (PEI), polyarylate (PAR), polysulfone (PSO), polyamide (PA), polycarbonate (PC), styrene-maleic anhydride (SMA), chorinated PVC (CPVC), poly(methylmethacrylate) (PMMA), styrene-acrylonitrile (SAN), polystyrene (PS), acrylonitrile-butadiene-styrene (PS), acrylonitrile-butadiene-styrene (ABS), poly(ethyleneterephthalate) (PET),

poly(vinylchloride) (PVC), polyetherketone (PEK), polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE), poly(phenylene sulfide) (PPS), liquid crystal polymer (CCP), nylon-6,6, nylon-6, nylon-6,12, nylon-11, nylon 12, acetal resin, low and high density polypropylene (PP), high density polyethylene (HDPE), low density polyethylene (LDPE), polystyrene, ethylene-vinyl acetate, poly-vinyl-acetate and polyacrylic.

13. A specimen cup as in claim 10 wherein said specialty plastics is selected from the group comprising fluorocarbon polymers and infusible film products, and Upilex polyimide film.

14. A specimen cup as in claim 10 wherein said thermosets is selected from the group comprising phenolics, epoxies, urea-formaldehyde and silicones.

15. A specimen cup as in claim 10 wherein said engineering plastics is selected from the group comprising acetyl resins, polyamide, poly-etherimides, polyesters, liquid crystal polymers, polycarbonate resins, poly(phenylene ether) alloys, polysulfone resins and polyamideimide resins.

16. A specimen cup as in claim 1 wherein said cassette draw said testing fluid specimen from said cassette's bottom through a pooling area.

7. ABSTRACT

A specimen cup (100) has slide-in cassette (102) hermetically sealed in a chamber (104), with a outer partition being transparent. The cassette comprised chemical test strips (106) used to provide testing of drugs of abuse or other chemical or biological substances. The cassette is designed to draw urine up from the front bottom of the cup, thereby reduces the amount of urine required to perform the test. Further the cassette is designed to form isolated test channels through the use of strategically placed vertical and horizontal bars which are hermetically sealed. The cup further comprises a spill prevention flap or float (108) and an optionally enlarged sample collection portion (110) for its operation. The windows of the test cassette are covered with transparent fluid-resistant plate to prevent urine from accidentally spill onto the strips.

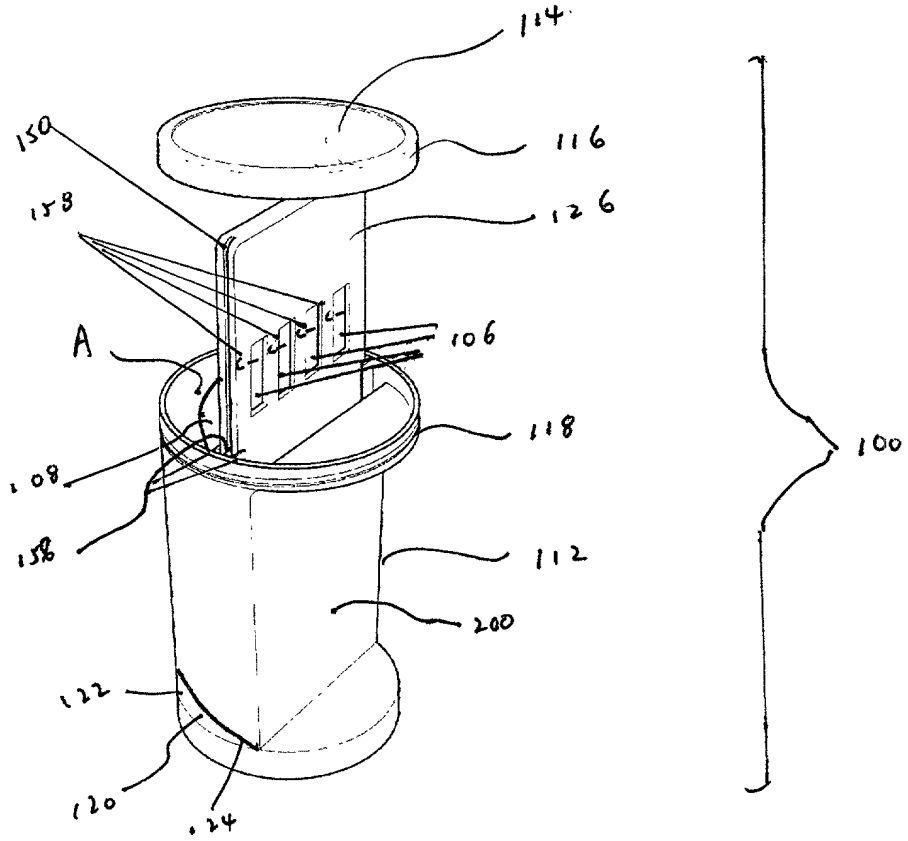

FIG. 1.

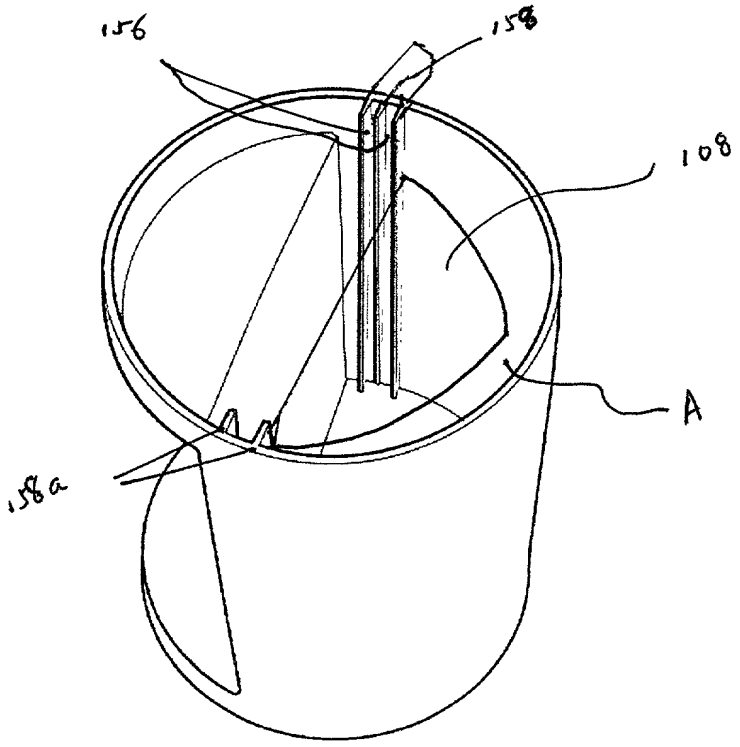

FIG. 2

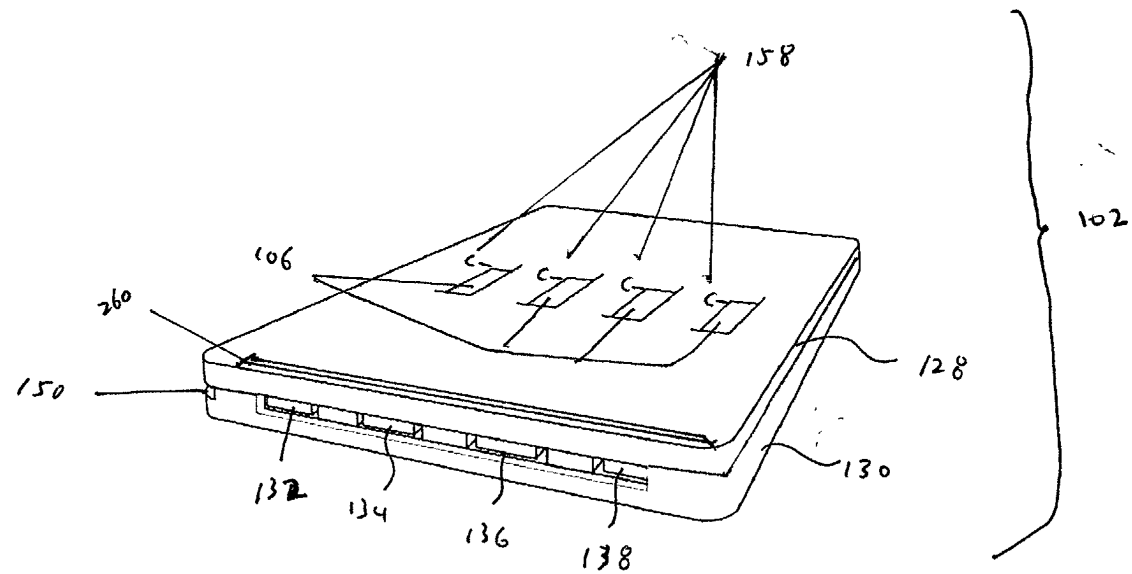

FIG. 3.

Attorney's Docket No. 1002-111-APP **PATENT**

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

☒ original.

☐ design.

☐ supplemental.

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

☐ national stage of PCT.

NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

☐ divisional.

☐ continuation.

☐ continuation-in-part (C-I-P).

INVENTORSHIP IDENTIFICATION

WARNING: *If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

SLIDE-IN CASSETTE FOR A CUP FOR TESTING OF DRUGS OF ABUSE

SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b) or (c))

(a) ☒ is attached hereto.

NOTE: "The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1177 O.G. 60).

(b) ☐ was filed on _____, as ☐ Serial No. 0 /_____ or ☐ _____ and was amended on _____ *(if applicable).*

NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(1) name of inventor(s), and application number (consisting of the series code and the serial number; e.g.,08/123,456);

"(2) name of inventor(s), serial number and filing date;

"(3) name of inventor(s) and attorney docket number which was on the specification as filed;

"(4) name of inventor(s), title which was on the specification as filed and filing date;

"(5) name of inventor(s), title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

"(6) name of inventor(s), title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number; e.g.,08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."

Notice of July 13, 1995 (1177 O.G. 60).

(c) ☐ was described and claimed in PCT International Application No. _____, filed on _____ and as amended under PCT Article 19 on _____ *(if any).*

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

(also check the following items, if desired)

☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119(a)–(d))

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)–(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ☒ no such applications have been filed.

(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

(34 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE
_____ /_____	_____
_____ /_____	_____
_____ /_____	_____

CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S) UNDER 35 U.S.C. 120

☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), *IF ANY*, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: *If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.*

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

Ying-kit Lau, J.D., Ph.D. Registration number: 35760

(check the following item, if applicable)

☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO

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DIRECT TELEPHONE CALLS TO:
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(213) 680-9888
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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

Jeffery A. Konecke
(GIVEN NAME) *(MIDDLE INITIAL OR NAME)* *FAMILY (OR LAST NAME)*

Inventor's signature Jeffery A. Konecke

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(GIVEN NAME) *(MIDDLE INITIAL OR NAME)* *FAMILY (OR LAST NAME)*

Inventor's signature

Date **Country of Citizenship**

Residence N/A

Post Office Address

Full name of third joint inventor, if any

(GIVEN NAME) *(MIDDLE INITIAL OR NAME)* *FAMILY (OR LAST NAME)*

Inventor's signature

Date **Country of Citizenship**

Residence N/A

Post Office Address

(check proper box(es) for any of the following added page(s) that form a part of this declaration)

☐ **Signature** for fourth and subsequent joint inventors. *Number of pages added* _____.

* * *

☐ **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* _____.

* * *

☐ **Signature** for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added* _____

* * *

☐ Added page for **signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 CFR 1.47)

* * *

☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.

☐ Number of pages added _____

* * *

☐ Authorization of attorney(s) to accept and follow instructions from representative.

* * *

(if no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)

☒ This declaration ends with this page.